DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

23 AUG 2001

MCMR-RCQ (70)

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Command Policy 2001-04, Ethical Use of Human Cadavers in USAMRMC Research

1. References.

a. 32 CFR 219, Protection of Human Subjects

b. AR 70-25, Use of Volunteers as Subjects of Research, 25 January 1990

c. Uniform Anatomical Gift Act, drafted by National Conference of Commissioners of Uniform State Laws, 1987

2. Purpose. This memorandum establishes the U.S. Army Medical Research and Materiel Command (USAMRMC) policy for the proper procurement, treatment, and disposition of human cadavers in any research conducted or managed by USAMRMC (intramural and extramural), in any research conducted in USAMRMC facilities, or in any research conducted by USAMRMC personnel as part of their USAMRMC duties.

a. USAMRMC believes that it is necessary to provide oversight of research using human cadavers. Human cadavers should be treated with respect, and should not be used in research if alternatives are available.

b. Neither the Common Rule (adopted by the Department of Defense as 32 CFR 219) nor AR 70-25 applies to research using human cadavers. Both of these regulations apply to "human subjects" and both define "human subject" as a "living individual". Though Institutional Review Board (IRB) review is not mandated by the Common Rule or AR 70-25 for research using human cadavers, the existence of ethical concerns and regulatory requirements in research using human cadavers, and the often high-profile nature of such research, counsel in favor of requiring IRB review as indicated in paragraph 3, below.

3. Applicability and Scope. This policy is applicable to all research using human cadavers that is conducted or managed by USAMRMC (intramural and extramural), conducted in USAMRMC facilities, or conducted by USAMRMC personnel as part of their USAMRMC duties.

a. The term "cadaver" means a deceased person or portion thereof. The term "cadaver" includes organs, tissue, eyes, bones, arteries, blood, fluid or other portion of a deceased person. The term "cadaver" does not include portions of an individual, such as tissue or blood, that were removed from the individual for research purposes while the individual was still alive (for example, if a subject of an earlier research protocol donated tissue taken from him or her during that protocol for use in future research protocols, that tissue is not a "cadaver" under this policy, regardless of whether the individual is still living or has died prior to the current research protocol). This policy is meant to apply only to research using donations that take effect upon or after the death of an individual.

b. The term "research" has the same definition as in 32 CFR 219: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

4. Policy.

a. Intramural research protocols involving the use of human cadavers require review and recommendation for approval by the local Scientific Review Committee (SRC) and Human Use Review Committee (HURC). If there is no formal SRC, scientific review is still necessary, but may be done by some other qualified committee or personnel. Extramural research protocols require scientific review. Extramural research protocols also must receive review and approval from the institution's IRB if it is the policy of that IRB to review research involving the use of human cadavers. If approved at the local level, the protocol must be forwarded to the Surgeon General's Human Subjects Research Review Board (HSRRB) for review. No research that is subject to this policy will be conducted without approval from the HSRRB, either through expedited review or full Board review if deemed necessary.

b. For intramural research, the Principal Investigator (PI) will provide copies of state and local laws (or, for research in a foreign country or U.S. territory, that country's or territory's laws) regarding procurement, treatment, and disposition of the human cadavers requested for the research protocol to the respective human use committees involved in the review and approval of the PI's research protocol. Note that the Uniform Anatomical Gift Act has been adopted in some form in all states and the District of Columbia. The HURC will ensure that any relevant laboratory/institution policies are being and will be followed. For extramural research, either the PI or the IRB will provide copies of state and local laws (or foreign or U.S. territory laws) to the HSRRB. Neither the HURC nor the HSRRB will approve any research protocol unless it is satisfied that applicable laws regarding human cadavers have been and are being followed.

c. In addition to copies of applicable laws, the PI will provide documentation indicating:

(1) that cadavers will be properly and legally procured;

(2) that vendors will be informed of the intended use of the cadavers;

(3) that cadavers will be used in a manner consistent with the intent of the donor. Any restrictions on the use of cadavers by the donor must be honored in the protocol. The wishes of donor's next of kin will be considered if and as required by applicable laws; and

(4) that cadavers were tested for at least the following communicable diseases: hepatitis B and HIV. The documentation must indicate whether tests were positive for any cadaver, and if so, for what diseases. Research staff and any personnel who may come in contact with a cadaver that tested positive for a communicable disease must be made aware that the cadaver tested positive for the disease. Cadavers that test positive for given diseases may or may not be appropriate for the research protocol in question; it is not expressly prohibited to use in research cadavers that have tested positive. If the PI believes that testing is impossible or unnecessary for a given protocol, the PI must provide an explanation that satisfies the HURC/IRB and HSRRB.

d. Protocols involving the use of human cadavers will include specific procedures for the treatment, storage, and disposal of human cadavers by the research staff and other institution personnel. The HURC and HSRRB must be satisfied that these procedures are appropriate and ethical. For example, the HURC and HSRRB should consider whether the protocol provides for proper transportation and refrigeration of cadavers; whether the protocol limits access to cadavers to those with a need for access and provides for security of the cadavers; whether the protocol provides for disposal of the cadavers in accordance with stated wishes of the donor or next of kin; and whether the protocol provides for maintaining confidentiality of identity of cadavers. While compliance with state and local laws may often or sometimes be sufficient to satisfy the HURC or HSRRB as to the ethical treatment of the cadavers, there may be certain research protocols (or certain states) for which measures beyond mere compliance with state and local laws are deemed necessary to ensure that cadavers are treated ethically.

e. The HURC and the HSRRB will only approve research using human cadavers if:

(1) the research cannot be successfully conducted without using human cadavers; and

(2) benefits of the research are significant enough to justify the use of human cadavers; and

(3) the protocol considers whether there is a likelihood of psychological harm to research staff and other personnel due to the nature of the work with human cadavers in the protocol, and, if so, whether the protocol has procedures in place to minimize such harm. The HURC/IRB and HSRRB will determine if the protocol should include a consent document that informs research staff and other personnel of the nature of the experiment, the use of human cadavers, and the possible risk of mental or emotional distress due to involvement in the experiment. Such a consent form may not be necessary in all protocols involving human cadavers.

f. The HURC or the HSRRB may require researchers to undergo training on ethical issues in human cadaver research. If it requires such training, the HURC or the HSRRB must specify what training it feels is necessary. The PI must then provide evidence that this training has been completed.

5. Implementation. Laboratory/Institute commanders will ensure that research involving human cadavers does not commence prior to notification of final approval of the HSRRB. DOD-sponsored extramural research involving human cadavers cannot commence until final approval of HSRRB is received by the institution through the Contract Officer/Specialist, USAMRAA.

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Commanding

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